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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/813,271	03/20/2001	Nico Cerletti	4-20039C/C1C1/USN	2623
1095	7590	07/19/2004	EXAMINER	
			ROMEO, DAVID S	
			ART UNIT	PAPER NUMBER
			1647	

DATE MAILED: 07/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.	09/813,271	Applicant(s)	CERLETTI, NICO
Examiner	David S Romeo	Art Unit	1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

1) Responsive to communication(s) filed on 23 April 2004.  
2a) This action is FINAL.      2b) This action is non-final.  
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

4) Claim(s) 26-32 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
5) Claim(s) \_\_\_\_\_ is/are allowed.  
6) Claim(s) 26-32 is/are rejected.  
7) Claim(s) \_\_\_\_\_ is/are objected to.  
8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

9) The specification is objected to by the Examiner.  
10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
    Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
    a) All    b) Some \* c) None of:  
    1. Certified copies of the priority documents have been received.  
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

1) Notice of References Cited (PTO-892)  
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
    Paper No(s)/Mail Date \_\_\_\_\_

4) Interview Summary (PTO-413)  
    Paper No(s)/Mail Date. \_\_\_\_\_  
5) Notice of Informal Patent Application (PTO-152)  
6) Other: \_\_\_\_\_

**DETAILED ACTION**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action 5 has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 04/23/2004 has been entered.

Claims 26-32 are pending and being examined.

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The terminal disclaimer filed on 04/23/2004 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of 6,057,430 has been reviewed and is accepted. The terminal disclaimer has been recorded.

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**Maintained Formal Matters, Objections, and/or Rejections:**

***Claim Rejections - 35 USC §§ 102, 103***

Claims 26-32 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Builder (a13) in view of Rudolf 20 (u13).

Claims 26-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Builder (a13) in view of Rudolf (u13).

Applicant argues that the claimed invention does not include the additional elements of Builder's folding buffer disclosed in Builder's claim 25. Applicant's arguments have been fully considered but they are not persuasive. Firstly, in a 35 U.S.C. 102(e)/103(a) rejection over a prior art patent, the reference patent is available for all that

5 it fairly discloses to one of ordinary skill in the art, regardless of what is claimed.

Secondly, no evidence has been offered that the additional ingredients in the buffer used in Builder's process affect the basic and novel characteristic of the claimed invention.

Thirdly, the transitional phrase "consisting essentially of" does not exclude the additional elements of Builder's folding buffer.

10       Applicant argues that Builder teaches away from the determinations made by Applicant, as disclosed on page 4, lines 4-7, of the present specification. Thus, there is no motivation to use Applicant's process in the Builder reference. Applicant's arguments have been fully considered but they are not persuasive. Evidence of secondary considerations, such as teaching away or lack of motivation, is irrelevant to 35 U.S.C.

15      102 rejections and thus cannot overcome a rejection so based. To the extent that Applicant's arguments pertain to the rejections under 35 U.S.C. § 103, these arguments are still not persuasive because the rejections under 35 U.S.C. § 103 pertain to the presence of reduced glutathione and a mixture of DMSO and DMF. Whereas Applicant's arguments pertain to the presence of a chaotropic. Thus, Applicant's arguments are not germane to the obviousness of reduced glutathione and a mixture of DMSO and DMF.

20      Furthermore, the present disclosure at page 4, lines 4-7, deals solely with attempts to refold TGF-β using chaotropic agents. However, Builder's process does not rely solely on the presence of a chaotropic agent.

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Applicant argues that Rudolf does not teach a process for refolding TGF- $\beta$ ; that Rudolf teaches the empirical nature of protein refolding; that ribonuclease, as taught by Rudolf, and IGF-I, as taught by Builder, are not comparable to TGF- $\beta$ , and therefore there was no reasonable expectation of success. Applicant's arguments have been fully considered but they are not persuasive. Builder inherently discloses reduced glutathione. Builder expressly teaches the refolding of TGF- $\beta$ s. Evidence of secondary considerations, such as no reasonable expectation of success, is irrelevant to 35 U.S.C. 102 rejections and thus cannot overcome a rejection so based. Alternatively, it would have been obvious to one of ordinary skill in the art at the time of Applicants' invention to use reduced glutathione. Applicant's arguments are not germane to the motivation to use reduced glutathione. Furthermore, both Builder and Rudolf are in the field of applicant's endeavor, i.e., protein refolding, and are therefore reasonably pertinent to the particular problem with which Applicant is concerned. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references.

### ***Conclusion***

No claims are allowable.

20 ANY INQUIRY CONCERNING THIS COMMUNICATION OR EARLIER COMMUNICATIONS FROM THE EXAMINER SHOULD BE DIRECTED TO DAVID S. ROMEO WHOSE TELEPHONE NUMBER IS (571) 272-0890. THE EXAMINER CAN NORMALLY BE REACHED ON MONDAY THROUGH FRIDAY FROM 7:30 A.M. TO 4:00 P.M. IF ATTEMPTS TO REACH THE EXAMINER BY TELEPHONE ARE UNSUCCESSFUL, THE EXAMINER'S SUPERVISOR, BRENDA BRUMBACK, CAN BE REACHED ON (571)272-0961.  
IF SUBMITTING OFFICIAL CORRESPONDENCE BY FAX, APPLICANTS ARE ENCOURAGED TO SUBMIT OFFICIAL CORRESPONDENCE TO THE FOLLOWING TC 1600 BEFORE AND AFTER FINAL RIGHTFAX NUMBERS:  
25 BEFORE FINAL (703) 872-9306  
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CUSTOMERS ARE ALSO ADVISED TO USE CERTIFICATE OF FACSIMILE PROCEDURES WHEN SUBMITTING A REPLY TO A NON-FINAL OR FINAL OFFICE ACTION BY FACSIMILE (SEE 37 CFR 1.6 AND 1.8).  
30 FAXED DRAFT OR INFORMAL COMMUNICATIONS SHOULD BE DIRECTED TO THE EXAMINER AT (571) 273-0890.

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ANY INQUIRY OF A GENERAL NATURE OR RELATING TO THE STATUS OF THIS APPLICATION OR PROCEEDING SHOULD BE  
DIRECTED TO THE GROUP RECEPTIONIST WHOSE TELEPHONE NUMBER IS (703) 308-0196.

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DAVID ROMEO  
PRIMARY EXAMINER  
ART UNIT 1647

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DSR

JULY 15, 2004